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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,172	01/04/2000	Andreas Bohle	10890-2MIS:J	3048

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,172

Applicant(s)

BOHLE ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,8-16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-16 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5-21-04 has been entered.

The amendment and response filed on 5-21-2004 are acknowledged. Claims 1, 4, 8-9, 11-16 and 23 have been amended. Claims 2-3 have been amended. Claims 1, 4, 8-16 and 20-23 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1-4, 8-12, 16 and 23 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of **Bacillus Calmette-Guerin (BCG)** for the therapeutic treatment of condylomata acuminata, does not reasonably provide enablement for the use of **all Mycobacterium** species/strains for the therapeutic treatment of **all** disease conditions caused by papilloma virus infections is withdrawn in light of the amendment thereto.

The rejection of claims 1-4 and 8-15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite as they are lacking in positive active steps of the methods is

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withdrawn in light of the amendment to amendment thereto. The cancellation of claims 2-3 has rendered the rejection of said claims moot.

The rejection of claims 1, 11-13 and 16 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "area of infection" is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "treatment dose" is withdrawn in light of the amendment thereto.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the confusing language used in reciting the multiple ranges that encompass the limitations of the claim is withdrawn in light of the amendment thereto.

The rejection of claims 1, 2 and 9 under 35 U.S.C. 102(b) as being anticipated by Herr et al. (Journal of Urology Vol. 141, pages 22-29, 1989) is withdrawn in light of the amendment thereto. Herr et al. do not disclose the use of BCG to treat condylomata acuminata and hence cannot anticipate the rejected claims.

The rejection of claims 1-4, 8-16 and 20-23 under 35 U.S.C. 103(a) as being unpatentable over Herr et al. (Journal of Urology Vol. 141, pages 22-29, 1989) in view of Morton (GB2179858A) is withdrawn in light of the amendment thereto.

New Claim Objections

Claim 8 is objected to because of the following informalities: claim 8 recites the phrase "from about 1 to about 30 days for applications more than one". While one can discern what is being claimed, the claim language is grammatically clumsy. It is

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suggested that the aforementioned phrase be amended to read “from about 1 to about 30 days where the applications number more than one” in order to increase claim clarity.

Appropriate correction is required.

Claims 20-23 are objected to as being dependent on rejected claims.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 8-16, 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11-16 and 23 are rendered vague and indefinite by the use of the phrase “to the infection”. It is unclear what is meant by said phrase since the instant claims are drawn to methods of treating condylomata acuminata. Condylomata acuminata is a projecting warty growth on the external genitals or the anus caused by infection with the human papillomavirus (HPV). While caused by an infectious agent, condylomata acuminata is not generally considered an infection itself. Rather, condylomata acuminata is a condition or symptom of infection. Therefore, it is unclear to what “infection” Applicant is referring. Moreover, it is unclear what portion of the body is encompassed by “the infection”. It would be remedial, if the instant claims were amended to recite “to the affected area” in lieu of the phrase “to the infection”.

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Claims 8 and 9 are rendered vague and indefinite by the use of the phrase “of the infection”. It is unclear what is meant by said phrase since the instant claims are drawn to methods of treating condylomata acuminata. Condylomata acuminata is a projecting warty growth on the external genitals or the anus caused by infection with the human papillomavirus (HPV). While caused by an infectious agent, condylomata acuminata is not generally considered an infection itself. Rather, condylomata acuminata is a condition or symptom of infection. Therefore, it is unclear to what “infection” Applicant is referring. Moreover, it is unclear what portion of the body is encompassed by “the infection” or how it could be “treated” using a method comprising ablative surgery (claim 9). It would be remedial, if the instant claims were amended to recite “to the affected area” in lieu of the phrase “of the infection”.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Brandau et al. (Urological Research (1997) Vol. 25 No.1, page 94).

Brandau et al. disclose the use of Bacillus Calmette-Guerin (BCG) as a treatment for bladder tumors. Brandau et al further disclose the use of a keratolytic agent to alleviate the side effects of the BCG wherein said keratolytic agent is salicylic acid.

Brandau et al. differ from the instant invention in that they do not explicitly disclose the use of BCG and salicylic acid in the same composition.

It would have been obvious for one of skill in the art at the time the invention was made to combine BCG and salicylic acid in a single composition in order to simplify treatment protocols.

One would have had a reasonable expectation of success since the combination of an adjuvant (salicylic acid) with the “active” component (BCG) is common practice within the art.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Zeman
August 2, 2004